Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation

Part D Payment Modernization Model
Request for Applications

Contents

1. Background and General Information

1.1 Model Scope and General Approach

The Centers for Medicare & Medicaid Services (CMS) is seeking applications from Prescription Drug Plans (PDPs) and Medicare Advantage Organizations offering Medicare Advantage-Prescription Drug Plans (MA-PDs) to participate in the Part D Payment Modernization Model (PDPM Model or "the Model"). This request for applications (RFA) outlines model design elements, model eligibility criteria, and additional model details for organizations interested in applying. CMS is conducting this model test through the Center for Medicare and Medicaid Innovation (Innovation Center) under Section 1115A of the Social Security Act.

In order to address the high list price and high beneficiary out-of-pocket costs of prescription drugs, CMS is testing the impact of an updated Medicare Part D payment structure. Through testing a change to the Part D payment structure and providing additional programmatic flexibilities, including allowing for Part D Rewards and Incentives programs, the Model tests how modernizing the Part D payment structure incentivizes lower federal reinsurance subsidy spending specifically, and overall Part D spending and beneficiary out-of-pocket costs generally.

The voluntary, five-year Model modernizes the Part D payment structure through increasing plan sponsor liability in the catastrophic phase of Part D to address rising federal reinsurance subsidy spending. Eligible PDPs and MA-PDs that are approved to participate in the model will take two-sided risk for CMS's federal reinsurance subsidy (80 percent of catastrophic phase liability), allowing for performance-based payments from, or additional payments to, CMS based on spending. The Model will also permit participants to use additional programmatic tools, including Part D Rewards and Incentives programs, to increase engagement between plans and their enrollees, which will promote better enrollee understanding of the Part D benefit, out-of-pocket costs, and clinically equivalent therapeutic options. This will, in turn, increase access, adherence, and affordability.

By balancing plan sponsors' acceptance of additional catastrophic phase risk in a competitive Part D market with the potential earning of performance-based payments, the model will test how participating plan sponsors can maintain and enhance their enrollees' access to, and the affordability of, covered Part D drugs, while better managing overall spending. Overall, through the Model, CMS will understand the impact of better aligning risk-incentives and any additional flexibilities necessary for clinically-based utilization management.

1.2 Statutory Authority

Section 1115A of the Social Security Act (the Act) (42 U.S.C. § 1315a, added by Section 3021 of the Patient Protection and Affordable Care Act) authorizes CMS to test innovative healthcare payment and service delivery models that have the potential to lower Medicare, Medicaid, and Children's Health Insurance Program (CHIP) spending while maintaining or improving the quality of beneficiaries' care.

1.3 Waiver Authority

Under Section 1115A(d)(1) of the Act, the Secretary of Health and Human Services may waive such requirements of Titles XI and XVIII and of Sections 1902(a)(1), 1902(a)(13), and

1903(m)(2)(A)(iii) as may be necessary solely for purposes of carrying out section 1115A with respect to testing models described in section 1115A(b). For this model and consistent with this standard, the Secretary may consider issuing waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the Act.

1.4 Medicare Program and Payment Waivers

In support of the Part D Payment Modernization Model, the Secretary intends to waive certain requirements under Title XVIII of the Social Security Act and its implementing regulations for purposes of testing the Model. No waivers of any kind are being issued in this document, which merely describes the waivers contemplated at this time for the Part D Payment Modernization Model. Programmatic waivers under consideration are the following:

Additional Payments to Plan Sponsors: Section 1860D-15(a) of the Social Security Act and 42 C.F.R. Section 423.329(a), to the extent necessary to allow CMS to make additional payments, including but not limited to performance based payments, to plans participating in the Model.

Part D Catastrophic Phase Liability Distribution: Section 1860D-15(b) of the Social Security Act and 42 C.F.R. Section 423.329(c), to the extent necessary to allow plan sponsors to take two-sided risk on the federal reinsurance subsidy and modifying the method for calculating reinsurance payments.

Part D Bid and Payment Data: Section 1860D-15(f) to the extent necessary to permit CMS to use Part D bid and payment data for purposes of conducting the model test.

1.5 Fraud and Abuse Waivers

As noted above, for this Model and consistent with the standard set forth in Section 1115A(d)(1), the Secretary may consider issuing waivers of certain fraud and abuse provisions in Sections 1128A, 1128B, and 1877 of the Act. Fraud or abuse waivers are not being issued in this document; fraud and abuse waivers, if any, would be set forth in separately issued documentation. Thus, notwithstanding any other provisions of this RFA, all individuals and entities must comply with all applicable laws and regulations, except as explicitly provided in any such separately documented waiver issued pursuant to Section 1115A(d)(1) specifically for the Part D Payment Modernization Model. Any such waiver would apply solely to the Part D Payment Modernization Model and could differ in scope or design from waivers granted for other programs or models.

2. Description of Model

2.1 Purpose and Concept

U.S. prescription drug spending and patient out-of-pocket costs are a growing area of public discussion and policy interest. While prescription drugs for high prevalence chronic conditions in the U.S., such as cardiovascular disease, predominated Part D utilization and spending in the benefit's early years, advances in research and development have allowed for cures and treatments with significantly different utilization patterns and costs. The economics of pricing for these and other drugs has also changed, with high list prices shifting spending for more Medicare beneficiaries into the catastrophic coverage phase of the Part D benefit. In the catastrophic

coverage phase under the defined standard benefit, plan sponsors assume 15 percent liability, beneficiaries assume 5 percent, and the government pays 80 percent of costs after direct and indirect remuneration through a fully reconciled, open-ended federal reinsurance subsidy. Given advances in the biopharmaceutical industry, and the resultant costs and benefits of therapies that Medicare beneficiaries rely on, there is broad consensus among stakeholders that the catastrophic coverage phase of the Part D benefit should be modernized. One key policy theme is to modernize Part D by updating the Part D payment structure, which has been outlined in numerous reports, including the Administration's blueprint to lower drug prices, the HHS Office of Inspector General's (OIG) report on high-price drugs, and MedPAC's June 2016 Report on *Improving Medicare Part D*.[1,2,3] Through this Model, CMS is testing the impact of increased Part D sponsor liability in the catastrophic coverage phase on federal reinsurance subsidy spending.

2.2 Model Design Elements

The Part D Payment Modernization Model tests the impact of re-designing the catastrophic coverage phase of the Part D benefit to increase Part D plan sponsor management of prescription drug prices and spending. If successful, this Model will decrease total Part D spending, including in the catastrophic phase, and improve beneficiary access to, and the affordability of, prescription drugs by targeting key drivers of increased Part D drug spending, including the high list price of new brand and specialty therapies, increasing the transparency of manufacturers' drug prices.

Payment Model Design Elements

Current Part D bid, payment, and reconciliation processes will continue to apply. The current 15 percent catastrophic coverage phase liability included in the direct subsidy will continue to be bid as part of the direct subsidy and reconciled as usual under current law. The 80 percent catastrophic phase liability currently bid as prospective federal reinsurance will continue to be bid as prospective federal reinsurance and reconciled fully to actual spending. Final, reconciled federal reinsurance subsidy spending will then be assessed against a benchmark, as described below, to determine organization performance. The current 5 percent beneficiary liability in the catastrophic phase under the standard benefit will continue to apply.

As part of the model test, following a plan year, CMS will calculate a spending target benchmark for that plan year. All federal reinsurance subsidy spending for participating plan benefit packages (PBPs) will be aggregated by parent organization and product type to create spending target benchmarks – one for the participant's PDPs and one for its MA-PDs. The spending target benchmark will project what plan federal reinsurance spending would have been in the absence of the Model and will be developed using a multivariate approach based on product type (PDP or MA-PD), percentage of enrollment that receive the low-income subsidy, non-model participating organization federal reinsurance trends, regional trends, organization RxHCC risk adjustment

[1] American Patients First. The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. May 2018. https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf
[2] Department of Health and Human Services Office of Inspector General. High-Price Drugs are Increasing Federal Payments for Medicare Part D Catastrophic Coverage. January 2017. https://oig.hhs.gov/oei/reports/oei-02-16-00270.pdf
[3] Medicare Payment Advisory Commission (MedPAC). Improving Medicare Part D. June 2016. http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf

scores, formulary and type of plan offering, and other factors as deemed appropriate by CMS. Historical and projected per capita federal reinsurance subsidy trends are available in the Medicare Trustees Report (Table IV.B9.–Incurred Reimbursement Amounts per Enrollee for Part D Expenditures). Additional detail on the spending target benchmark methodology will be provided to provisionally approved organizations who must indicate their participation in the Model with their bid submission for the CY 2020 plan year.

As noted above, spending target benchmarks will be aggregated at the parent organization level by product type (PDP or MA-PD). Based on the organization's reconciled actual federal reinsurance subsidy expenditures, CMS will make performance-based payments when a plan shows favorable performance (i.e. savings). Through performance-based payments, CMS will share savings on federal reinsurance subsidy spending relative to the spending target benchmark with participating plans. CMS will share 30 percent of any savings up to 3 percent of total federal reinsurance subsidy spending savings, and 50 percent of any savings above 3 percent. Plans will be subject to a 10 percent penalty for any federal reinsurance subsidy spending above their spending target benchmark. Determinations of any payments from or due to CMS will be made once all available Part D Prescription Drug Event, direct and indirect remuneration, enrollment, and risk adjustment data are available and federal reinsurance subsidy reconciliation is finalized.

Programmatic Model Design Elements

As part of taking additional risk for managing spending in the catastrophic phase, and to encourage model participant engagement with their enrollees, CMS is permitting model participants to propose Part D Rewards and Incentives (RI) programs that, in connection with medication use, focus on promoting improved health, medication adherence, and the efficient use of health care resources. All proposed Part D RI Programs need to be designed to encourage enrollees to use Part D covered medications in ways that lead to improvement in at least one of these three areas (i.e., health outcomes, medication adherence, and the efficient use of health care resources). Part D plan sponsors should include any Part D RI Programs in their application for approval by CMS. Cost associated with approved Part D RI Programs would be included in the bid submission as a non-benefit expense as part of the plan's program description for applicable Plan Benefit Packages.

To supplement the general parameters above, CMS has developed the following to guide plans in developing their proposed Part D RI Programs.

Permissible Part D RI Program Designs Generally

1. Part D RI Programs may be designed to target enrollees with specific conditions or enrollees who would benefit from participating in disease state management programs.

2. Part D RI Programs that provide rewards and incentives for participating in plan sponsor medication therapy management (MTM) programs.

3. Part D RI Programs that provide rewards and incentives for enrollees that participate in preventive health services, such as receiving Part D covered vaccines.

4. Part D RI Programs that allow enrollees to better understand their Part D plan benefit, costs, and clinically-appropriate coverage alternatives, including biosimilars and generics. Specifically, this includes Part D RI Programs that provide rewards and incentives to enrollees that participate in educational programs to improve their understanding of their Part D plan benefit, costs, and clinically-appropriate coverage alternatives.

Impermissible Part D RI Programs

1. Part D RI Programs that would reward enrollees for not taking any, or few, Part D covered drugs and vaccines. Part D sponsors may not structure a Part D RI Program to discourage clinically-indicated medication use.

2. Part D RI Programs that would largely serve to market the plan or to encourage beneficiaries to remain with a specific plan based on a reward and incentive. Part D sponsors may not use an RI program to, in any way, choose or solicit healthier enrollees over enrollees who the sponsors believe may be less healthy. Rewards and incentives may not be offered to potential enrollees under any circumstances.

3. RI Programs that discriminate against enrollees based on race, national origin, limited English proficiency, gender, disability, chronic disease, whether a person resides or receives services in an institutional setting, frailty status, health status, or other prohibited basis.

4. Part D RI Programs to be used to steer beneficiaries to mail service pharmacies, preferred pharmacies or any other specific network providers. Rewarding a beneficiary's choice of pharmacy is not an appropriate activity to influence through rewards and incentives, nor should choice of pharmacy negatively affect an enrollee's ability to earn rewards and incentives under a Part D RI Program.

5. Part D sponsors may not, in connection with a Part D RI Program, receive funding, in-kind resources, or any kind of payment provided by a drug manufacturer nor may the sponsor’s Part D RI Program make use of personnel affiliated with a manufacturer, manufacturer-financed coupons or discounts provided to a beneficiary, or manufacturer-supplied educational materials. Further, Part D sponsors may not, in connection with the Part D RI programs under this Model, receive funding, in-kind resources, or any kind of payment from pharmacies nor may a Part D sponsor’s program make use of personnel affiliated with a pharmacy, pharmacy-financed coupons, or discounts provided to a beneficiary, or pharmacy-supplied education materials.

Requirements for Part D RI Programs

1. Part D RI Programs must be complete by the end of a plan year. Part D RI Programs may not allow enrollees to carry over rewards and incentives from one contract year to the next.

2. Any rewards or incentives offered under Part D RI programs must be limited to a value that may be expected to impact enrollee behavior and may not exceed the value of the health-related service or activity. Part D sponsors must reasonably establish value for any pharmacist consultation, successful medication adherence, successful formulary compliance, or other CMS-approved health-related activity or service for which they offer rewards and incentives.

3. Notwithstanding the limited scope of any potential fraud and abuse waivers of the Part D Payment Modernization Model test, which are not being granted as part of the application, Part D RI Programs must comply with all fraud and abuse laws, including, when applicable, the anti-kickback statute and civil money penalty prohibiting inducements to beneficiaries.

4. Part D RI Programs are prohibited from providing rewards or incentives in the form of cash or other monetary rebates.

5. CMS will not approve or will terminate use by a participating plan of Part D RI Programs that largely serve to market the plan or to encourage beneficiaries to remain with a specific plan based on a reward and incentive. Rewards and incentives may not be used to decrease cost sharing or plan premiums.

6. Rewards and incentives must be tangible items that align with the purpose of the Part D RI Program and must directly benefit the enrollee. Part D sponsors have the flexibility to propose what may be offered as a reward or incentive, including gift cards and discount coupons as long as they are not transferable for cash and may not be used to directly or indirectly decrease cost sharing for medication(s) or plan premiums. However, a plan's charitable contribution made on behalf of the enrollee does not satisfy the CMS criteria as a permissible reward or incentive because the enrollee who earned the reward does not benefit from such a contribution by the sponsor. The use of points (which are not themselves tangible), however, to purchase a non-cash or cash equivalent reward does satisfy CMS criteria because the points are used by each enrollee to obtain a tangible reward that is of value to the enrollee.

7. Part D RI Programs that are designed to be won based on probability, including programs in which an enrollee may earn entries into a lottery or drawing in order to receive a reward or incentive of a significant value, are prohibited.

More generally, CMS will review all proposed Part D RI Programs based on the rationale and theory for the reward or incentive; the population of focus; how the plan defines the value of the reward to total cost of care; and the expected health outcomes and cost and savings effect of its proposed intervention. CMS, in its sole discretion, reserves the right to accept or reject any Part D RI Program proposal.

As part of model monitoring and evaluation, participating Part D sponsors that offer Part D RI Programs must submit to CMS the form and manner of any Part D RI Program it offers including the total expected and actual costs of the Part D RI Program; the value of the reward and

incentive and how the value was derived; the number of enrollees targeted under the Part D RI Program; the number of enrollees that received the reward or incentive, including trends over time; and any demographic or other information about the types of enrollees engaged; and any evaluation of the effectiveness of the program.

Additionally, if in the course of CMS monitoring it is determined that a Part D sponsor is not operating its Part D RI Program in compliance with the approved program, CMS may impose sanctions or civil monetary penalties on the Part D sponsor in accordance with §423.752(a)(5).

Additional Model Design Elements

CMS will provide approved model participants with guidance on any additional programmatic flexibilities that may be offered as part of the test, including the potential for additional formulary and non-formulary management options and changes, if any, to participant star rating measures and calculations.

CMS will make this information available to Part D sponsors that are provisionally approved to be in the Model test in order to ensure plan sponsors have adequate time to reflect any additional flexibilities in their 2020 Part D bids.

Further, included with provisional approval, CMS will provide model participants with information on model marketing restrictions and allowances, including changes, if any, to how participants will be presented in Medicare plan finder, as well as any changes to the *de minimis* policy (that is, the policy that permits Part D sponsors to waive a *de minimis* amount of premium in excess of the low-income premium subsidy amount) to allow model participants to waive a greater *de minimis* amount than non-model participants. Any increase in amount participating Part D sponsors may waive under the *de minimis* policy will be announced in the annual release of Part D National Average Monthly Bid Amount and other Part C & D bid information and operational guidance.

CMS will implement the PDPM Model test for a five-year performance period beginning on January 1, 2020 and continuing through December 31, 2024. Reconciliation for the final model year, and payment of any performance-based payments or assessment of any penalties is anticipated to occur in 2025 as part of 2024 reconciliation. CMS, in its sole discretion, may terminate the Model before December 31, 2024.

2.3 Geographic Scope

The Part D Payment Modernization Model will be open to eligible organizations nationally. Eligible Part D sponsors of PDPs applying in a region must include all of their plan benefit packages in that Part D region. Eligible MA organizations applying for one MA-PD PBP in a PDP region must include all MA-PD plans with service areas that are within the PDP region in whole or in part.

2.4 Plan Eligibility

Participation in the Model is voluntary. Except as described in the next paragraph, all PDP and MA-PD plans, including those that offer standard or alternative Part D coverage (defined standard,

actuarially equivalent standard, basic alternative, and enhanced alternative plans), are eligible to apply to participate in the Part D Payment Modernization Model.

Special needs plans, private fee-for-service plans, employer/union only direct contract plans (local coordinated care plans, prescription drug plans, private fee-for-service plans), section 1876 cost contract plans, section 1833 health care prepayment plans, PACE, Medicare-Medicaid plans, and religious fraternal benefit plans (local coordinated care plans and private fee-for-service plans) are not eligible for participation in the Model.

Part D sponsors will be required to submit all PBPs in the PDP regions for which they are applying for participation.

CMS reserves the right to reject proposals that, as determined solely through CMS' discretion, may pose an undue risk of harm to beneficiaries, or are inconsistent with the implementation and evaluation objectives of the model. This includes the right to reject, or terminate in the future, any organization that has failed to comply with CMS program integrity requirements, is subject to investigation or sanction, or fails to comply with the terms of the Model. CMS will not allow any organization under sanction, as described in 42 C.F.R. 422.750 and 42 C.F.R. 423.750, to participate in the Model. As part of the application, organizations must note if they are applying to include in the Model any PBP that is currently deemed to be "consistently low performing." CMS will require organizations to provide a rationale for how participation in the Model is consistent with the Model's aims and the plan's corrective action plan for addressing its current performance.

2.5 Changes to Model Design in Current or Future Model Years

CMS retains the right to modify any model policy or parameter on an annual basis, or more frequently, in accordance with procedures to be agreed upon in the Model's contractual addendum.

3. Quality and Performance Monitoring

As part of both model implementation and evaluation, CMS will monitor the impacts of the Model on cost and quality. Specifically, CMS will monitor the Model's impact on Part D spending, as well as how beneficiary access to covered Part D prescription drugs and the affordability of those prescription drugs is maintained or enhanced. A description of some dimensions CMS intends to monitor through the Model are below:

- **Prescription drug list price:** CMS may monitor and assess the extent to which list prices for Part D drugs change over the course of the Model;
- **Prescription drug net price:** CMS may monitor and assess the extent to which prices net of all direct and indirect remuneration are different between model participants and non-participants;
- **Prescription drug choice, quality, and access**: CMS may monitor and assess any changes or differences in formularies, complaints, 1-800-MEDICARE and the Medicare Complaint Tracking Module, Star ratings, and appeals and grievances for model participants and non-participants;

- **Part D drug utilization:** CMS may monitor and assess prescription drug event claims to determine the types and classes of medications that are utilized, including specialty tier, non-specialty tier brand, and generic, by enrollees in participating and non-participating plans;
- **Part B drug utilization and spending:** CMS may monitor any changes in Part B drug utilization and spending for model participants versus non-participants. CMS will investigate any material shift in utilization from Part D drugs to Part B drugs for an organization that is participating in the Model;
- **Parts A and B spending:** CMS may monitor and assess any differences in Parts A and B spending for enrollees in participating and non-participating plans;
- **Part D Bids and Payments:** CMS will review Part D bid data, including both the direct subsidy and prospective federal reinsurance subsidy, to reconciled, actual spending for model participants and non-participants;
- **Part D Premiums:** CMS may monitor and assess any Part D premium trends for model participants and non-participants;
- **Pharmacy Network:** CMS may monitor and assess the pharmacy network that participating and non-participating plans' enrollees utilize for their medications; and
- **Part D Rewards and Incentives Programs:** CMS will monitor and assess any changes in prescription drug utilization secondary to any Reward and Incentives programs; and other items as deemed appropriate to promote compliance with all model terms, beneficiary protections, and program integrity. Additionally, the Model will monitor and assess potential risks associated with Part D RI Programs by requiring participating plan sponsors to provide details specific to their RI programs.

While CMS will attempt to utilize existing data sources for both model implementation and evaluation activities, model participants will be required, where necessary, to provide information to CMS, including for the Part D Rewards and Incentives Program.

3.1 Enrollee Protections and Oversight

CMS will conduct regular monitoring to review model participant compliance with the terms of the model test. CMS will monitor for compliance using existing data sources to the extent practicable, and may seek plan-provided data or conduct site visits, particularly in response to high levels of complaints or other indicators of poor performance. CMS will closely monitor model implementation, to ensure that plan performance is consistent with model rules and approved proposals, and that the Model is not leading to any adverse beneficiary outcomes. This will include, but not necessarily be limited to, observing existing metrics of beneficiary access, outcomes, and satisfaction, and monitoring of increased beneficiary questions or complaints through 1-800-MEDICARE or the https://www.medicare.gov website. CMS will also monitor the impact the Model has on other CMS initiatives, such as the Part D Star Ratings.

CMS reserves the right to investigate an organization if there is evidence that indicates that the organization's participation in the model is adversely impacting enrollee quality of care, and exercise all available remedies in appropriate instances, including potential termination from the model test.

CMS retains the right to change any model policy on an annual basis or more frequently, in accordance with procedures and parameters that will be established in the Model's contractual addendum to the model participant's agreement with CMS for participation in the Part D program.

4. Evaluation

CMS will use an independent contractor to conduct an evaluation of the Part D Payment Modernization Model, which will examine the Model's implementation and assess the Model's impact on Medicare spending and the quality of care. All model participants will be required to participate in evaluation activities. CMS anticipates primarily relying on publicly available and existing data sources in the evaluation of the Model. In certain situations, however, model participants will be required to cooperate with primary data collection activities which may include participation in surveys, interviews, site visits, and other activities that CMS determines necessary to conduct a comprehensive formative and summation evaluation. When the evaluation uses non-publicly available data, CMS will report results at an aggregate-level so as to avoid the disclosure of private and sensitive data of specific model participants.

5. Application Process and Selection

Through this RFA, CMS is soliciting applications from eligible PDPs and MA-PDs to participate in the Part D Payment Modernization Model. The application process is competitive.

Model applicants are required at the time of application to specify the PBPs to be included the model test, and the PDP regions in which they will participate. Although participation is voluntary, PDP sponsors and MA-PD plans must respond to the RFA with sufficient detail and specificity for CMS to evaluate and understand the proposed theory of action that the plan sponsor will implement to manage catastrophic phase federal reinsurance spending under the Model.

As part of the application process, applicants will be required to provide the parent organization information, including Part D sponsor contract number, plan benefit package number(s), Star rating, as well as names, titles, and contact information.

Additionally, plans will provide qualitative and quantitative narrative descriptions of their proposed theory of action to decrease total Part D spending including, but not limited to, any pricing strategies that better address the list price of therapies, any proposed changes to a plan's formulary, which must ensure access consistent with formulary requirements, any expected decrease in premiums or non-low-income subsidy (LIS) enrollee out-of-pocket costs in the catastrophic phase of the benefit, any service or operational changes to ensure robust beneficiary access to the medications they need, including more expedient coverage review determinations or appeals, any expected impact to direct and indirect remuneration (DIR), any type of additional administrative or other costs that the plan expects to incur, as well as expected return on those costs, if any, and any other changes in Part D plan administration and management.

Applicants will attest that by applying, they agree to be part of the Model for the specific plan benefit package(s) and region(s) applied for. PBPs approved to participate will need to note in

HPMS their participation in the Model. Model participation terms will be provided in a contract addendum to the Model participant's agreement with CMS to participate in Part D.

5.1 Questions Regarding the Part D Payment Modernization Model Application

Questions regarding the PDPM Model or application process may be sent by email to PartDPaymentModel@cms.hhs.gov. CMS may publicly share responses to questions on the CMS Innovation Center website to ensure that all applicants have access to clarifying information regarding the Model and the application process.

5.2 Accessing the Online Application Portal

Interested organizations must apply to participate by responding to this RFA through the online application portal. CMS will communicate instructions for accessing the online application portal through the CMS HPMS system. Part D sponsors will be able to use the online portal to submit applications electronically. The online portal will include instructions for electronic signing and instructions for uploading any supplemental material electronically. Appendix A contains a template of the application questions that applicants will respond to through the online application portal.

5.3 Deadline for Application

The deadline for receipt of applications in response to this RFA is 11:59 PM EST on March 15, 2019. Applications must be complete and submitted using the online portal before the deadline.

5.4 Model Selection and Contracting

5.4.1 Selection

As part of the Model participant selection process, CMS will review Part D sponsors' applications for participation. Through the application process, CMS will ensure it retains the ability to create a comparison group for spending target benchmark and evaluation purposes. CMS will provide approved model participants notification of approval by the end of April 2019.

During the Model participant selection process, CMS will conduct program integrity screening and may decline to select otherwise qualified applicants on the basis of information found during a program integrity screen. Further, CMS reserves the right to reject any organization or plan on grounds required to preserve the integrity of the Medicare program, the welfare of beneficiaries, or the administration of the Part D Payment Modernization Model.

In accordance with Section 1115A(d)(2) of the Social Security Act, there is no administrative or judicial review of the selection of organizations, sites, or participants to test models.

5.4.2 Contracting

CMS will formally obligate participants to the terms of the Model test via a model-specific supplemental addendum to their current agreement with CMS for participation in Part D. That contract addendum will incorporate the requirements of the Model, as well as any policy documents issued by CMS to govern the model test. CMS expects to finalize and execute the addenda in September 2019 concurrently with the signing of other Part D contract documents.

Participating PDP sponsors and MA-PD plans will execute Part D contract addendum agreements that will include terms and conditions that vary from standard Part D requirements, such as:

- Applicability of specific program and payment waivers of statutory or regulatory requirements, and any limitations to such program and payment waivers
- Requirements for participation in CMS monitoring and evaluation activities

5.5 Timeline

A summary timeline for Part D Payment Modernization Model RFA and participant selection as part of the calendar year 2020 Medicare Part D bidding and contracting processes is provided below:

CY 2020 Part D Payment Modernization Model Milestones	
Date	**Milestone**
January 2019	Model Announced
February 2019	Application portal opens (announced on model website)
March 15, 2019	Application portal closes at 11:59pm EDT
April 2019	CMS provides provisional approval to accepted organizations
July/August 2019	Model agreements released to plan participants
September 2019	Model agreements fully executed (after Part D contracts)
January 2020	Model Year 1 Performance Period Begins

5.6 Withdrawal of Application

Applicant organizations seeking to withdraw an entire application or modify the geographic scope of a pending application, prior to their June bid submission, should submit a written request on the parent organization's letterhead that is signed by the primary point of contact named in the application submission. To submit a withdrawal request, applicants must send the request in a PDF format by email to PartDPaymentModel@cms.hhs.gov. The following information must be included in the letter:

- Legal Name of the Parent Organization
- Address
- Point of Contact information, including the person and their title named in the application
- Exact Description of the Nature of the Withdrawal (e.g., Withdrawal of entire application or change in selected markets)

5.7 Amendment of RFA

CMS may modify the terms of the PDPM model test or cancel it entirely in response to stakeholder comments or other factors. The terms set forth in this RFA may differ from the terms set forth in the final addendum for participation in the model test.

Appendix A – Application Template

In addition to providing applicant information by parent organization, Part D sponsor, and plan benefit package, applicants will have to provide qualitative and quantitative answers to the following questions, as well as certify participation in the Model for CY 2020, if approved by CMS. As part of answering question a. below, if an applicant is proposing a Part D Rewards and Incentives program, applicants must include a narrative description of that proposal, including the expected value of the reward or incentive, the rationale and evidence base, how the program will be implemented and monitored, how many enrollees are expected to be targeted and engaged, how much the applicant believes the program will cost, and what are the expected financial and clinical outcomes that the applicant is trying to impact based on the proposed Part D RI program.

a. Please provide a clear, concise narrative of intended changes to your Part D plan, including your proposed theory of change based on model parameters to better manage Part D prescription drug spending. *Any proposed Part D Rewards and Incentives Programs must be described in full in response to this question.*

b. Please provide the expected reduction, in percentage, per beneficiary per month, and total, in Part D spending that you believe you can achieve through these model parameters. Please include the basis for this projection.

The model application can be found at https://innovation.cms.gov/initiatives/part-d-payment-modernization-model/ and the Model is accepting applications until 11:59pm EDT on March 15, 2019.